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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,228	06/10/2002	John Scott Lloyd	056222-5008	3008

9629 7590 04/18/2005

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EXAMINER

CALAMITA, HEATHER

ART UNIT PAPER NUMBER

1637

DATE MAILED: 04/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/048,228

Applicant(s)

LLOYD ET AL.

Examiner

Heather G. Calamita, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 15-23 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 24 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 June 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/21/02
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION***Election/Restrictions***

1. Applicant's election with traverse of Group I, claims 1-14 and 24-25 filed 03/22/05 is acknowledged. Applicant's arguments filed 03/22/05 have been fully considered but they are not persuasive. Traversal was on the grounds that Clueziat et al. do not teach or suggest a probe molecule having, *inter alia*, "...a blocking moiety, there being from 0 to 50 nucleic acid bases between the blocking moiety and promoter sequence" as is claimed in amended claim 1. Applicant further argues Clueziat et al. do not anticipate the instant claim 1 and there is no motivational statement regarding obviousness provided.

The examiner maintains Group I and Group II are not linked by a special technical feature. Clueziat et al. teach the limitations recited in Claim 1. Clueziat et al. teach a probe with a sequence complementary to a target nucleic acid sequence (see col. 13 lines 15-17), a RNA polymerase promoter sequence and a blocking moiety from 0-50 bases from the promoter sequence (see col. 11 lines 9-13, and col. 12 lines 50-51). Clueziat et al. do anticipate and make obvious the instantly claimed probe, therefore Groups I and II do not have any linking special technical feature. Additionally, applicant is incorrect in asserting the instant claim 1 has been amended as only claims 2-14, 16-23 and 25 are newly amended.

Finally, applicants amendment of claim 15 to depend from claim 1 does not necessitate examination of Groups I and II together as it has been clearly evidenced by Clueziat et al. that instant claim 1 has no special technical feature that makes a contribution over the prior art. The examiner maintains the restriction requirement made previously, as each group is correctly separated and the restriction is **herein made final**. Claims 15-23 and 26, are withdrawn from further consideration by the examiner, 37 CFR 1.14(b), as being drawn to a non-elected invention. Pending claims to be examined are claims 1-14 and 24-25.

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Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-5, 6, 10-12 and 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Kacian et al. (WO 93/22461, 11/11/1993).

Kacian et al. teach (claim 1) a probe molecule comprising single stranded nucleic acid; comprising a single stranded sequence complementary to a target nucleic acid sequence (see p. 36 claim 1); a single strand of an RNA polymerase promoter sequence (see p. 36 claim 1), and a blocking moiety, there being from 0 to 50 nucleic acid bases between the blocking moiety and the promoter sequence (see p. 32, 33, 34 SEQ ID NOs 6, 10 and 14 respectively). These promoter primers have lengths between 46 and 55 nucleotides and therefore have a blocking moiety within between 1 and 50 nucleotides from the promoter. With regard to claim 2, Kacian et al. teach the template strand of an RNA polymerase promoter (see p. 36 claim 1). With regard to claims 3 and 4, Kacian et al. teach the probe comprising a -5

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sequence adjacent to the 3' end of the promoter sequence and +12 sequence adjacent to the 5' end of the promoter (see p. 32, 33, 34 SEQ ID NOs 6, 10 and 14 respectively). These promoter primers have lengths a +12 sequence adjacent to the 5' end of the promoter and a -5 sequence adjacent to the 3' end of the promoter. With regard to claim 5, Kacian et al. teach the probe when hybridized to the target, the 3' end of the target is extendible by a DNA polymerase (see p. 36 claim 1). With regard to claim 6, Kacian et al. teach the target complementary portion is located 3' of the promoter sequence (see p. 36 claim 1). With regard to claims 10 and 11, Kacian et al. teach the blocking moiety comprises a C₂-C₂₀ alkanediol residue (see p. 37 claim 7). With regard to claim 12, Kacian et al. teach a propanediol residue (see p. 37 claim 7). 3'-cordycepin is a propanediol. With regard to claims 24 and 25, Kacian et al. teach a kit comprising instructions, a buffer a DNA polymerase, an RNA polymerase, dNTPs, NTPs and a labeled binding partner (see p. 19 lines 36-37 and p. 20 lines 1-3).

3. Claims 1-14 and 24-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Clueziat et al. (USPN 5,874,260, 02/23/1999).

Clueziat et al. teach (claim 1) a probe molecule comprising single stranded nucleic acid; comprising a single stranded sequence complementary to a target nucleic acid sequence (see col. 13 lines 15-17); a single strand of an RNA polymerase promoter sequence (see col. 11 lines 9-13, and col. 12 lines 50-51), and a blocking moiety, there being from 0 to 50 nucleic acid bases between the blocking moiety and the promoter sequence (see col. 11 lines 9-13, and col. 12 lines 50-51). With regard to claim 2, Clueziat et al. teach the template strand of an RNA polymerase promoter (see col. 12 lines 50-52). With regard to claims 3 and 4, Clueziat et al. teach the probe comprising a -5 sequence adjacent to the 3' end of the promoter sequence and a +12 sequence adjacent to the 5' end of the promoter (see col. 33 SEQ ID NO: 1). With regard to claim 5, Clueziat et al. teach the probe when hybridized to the target, the 3' end of the target is extendible by a DNA polymerase (see col. 5 lines 26-30). With regard to claim 6, Clueziat et

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al. teach the target complementary portion is located 3' of the promoter sequence (see Figure 1 and col. 12 lines 50-53 and col. 13 lines 15-16). With regard to claims 7-9 Clueziat et al. teach a blocking moiety is located between position -22 and -35 (see col. 35 SEQ ID NO: 5). With regard to claims 10-12, Clueziat et al. teach hexaethylene glycol residue (see col. 33 SEQ ID NO: 2). Hexaethylene glycol is an alkylene blocking moiety having between 2 and 20 carbons. With regard to claims 13 and 14 Clueziat et al. teach PNA (see col. 5 lines 1-12). With regard to claims 24 and 25, Clueziat et al. teach a kit comprising instructions, a buffer a DNA polymerase, an RNA polymerase, dNTPs, NTPs and a labeled binding partner (see col. 19 lines 40-43).

Summary

4. No claims were allowed.

Correspondence

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 5:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at 571.272.0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number 571.273.8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to 571.272.0547.

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hgc


JEFFREY FREDMAN
PRIMARY EXAMINER

4/13/05